

REMARKS

Claims 2-17 have been cancelled without prejudice to the filing of continuing applications. Claims 1 and 18 have been amended and new claims 19-30 have been added. Support for the amendment to claim 1 and the new claims is found throughout the specification as originally filed. See, for example, page 12, line 27 to page 13, line 1; page 15, lines 1-2; and page 15, lines 24-26. No new matter is added herein.

The claims as amended meet the requirements of 35 U.S.C. § 112. Claims 18 and 30 are limited to the treatment of oral mucositis resulting from the treatment of cancer using radiation or chemotherapy. As noted by the Examiner in the Action, such treatment is enabled by the instant specification.

Claims 1-18 stand rejected under 35 U.S.C. §102(b) as being anticipated by or obvious under §103(a) in view of disclosure in published international application WO01/19362A2 (Orapharma).

In addition, claims 1-18 stand rejected for obviousness-type double patenting in view of co-pending application serial no. 11/230397, and in view of U.S. Patent Nos. 6,683,067, 6,893,665, and 6,946,118.

Applicants respectfully submit that the claims as amended are free of the art cited in the Action. The claims define novel subject matter that is not rendered obvious by the prior art. More specifically, the cited references lack any teaching of the use of a sugar, or the particular sugars lactose and mannitol

called for by the dependent claims, in a composition containing a tetracycline salt. Further, the particular pH required by the claims is novel, and taught away from in the cited references.

All the cited references share similar if not identical directions for the pH of the disclosed compositions. None of these references discloses a pH of from 6.5-9. Thus, the recitation in the amended claims of a pH from 6.5-9 clearly renders the claims novel. This pH range is also taught away from in the prior art, and renders the claims non-obvious. While a pH of up to 8 is said to be satisfactory, "a pH of 4 to 6.5 is most preferable" and "preparations having a higher pH are often unpleasant to use." See Orapharma at page 8, lines 20-23, and the cited U.S. Patent No. 6,683,067 at column 5, lines 28-32. Such disclosure in the prior art is clearly a teaching away from compositions having pH ranges called for by the amended claims. As a result, the claims are neither anticipated nor rendered obvious by the prior art.

Reconsideration and withdrawal of the anticipation and obviousness rejections are respectfully requested.

Applicants urge the Examiner to contact the Applicants' undersigned representative at (312) 913-0001 if the Examiner believes a discussion would expedite prosecution of this application.

Respectfully submitted,

Dated: July 18, 2007

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